



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|--|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/579,149 | 01/19/2007 | Mario Huesca | 13198.0007U1 | 8922 |
| 23859 | 7590 | 06/08/2009 | EXAMINER | |
| Ballard Spahr Andrews & Ingersoll, LLP | | | KLINKEL, KORTNEY L. | |
| SUITE 1000 | | | ART UNIT | PAPER NUMBER |
| 999 PEACHTREE STREET | | | | |
| ATLANTA, GA 30309-3915 | | | 1611 | |
| MAIL DATE | | DELIVERY MODE | | |
| 06/08/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/579,149 | Applicant(s) HUESCA ET AL. |
| | Examiner Kortney L. Kinkel | Art Unit 1611 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 March 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) 23, and 28-38 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21,22,24-27 and 39 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 12/15/2008
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Status

Receipt is acknowledged of remarks and claims filed 3/9/2009. No claims were amended. Claims 23 and 28-38 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Claims 21-39 are pending in the instant Office action.

Acknowledgement is also made of Applicant's submission of amendments to the specification page 29 and abstract dated 4/28/2008. Inadvertent typographical errors in chemical structures were corrected.

Claims 21-22, 24-27 and 39 are currently under consideration to the extent that they read on the elected species, namely the compound of claim 39. Please note also that examination of all 112 1st issues such as enablement and written description, of the claims have been limited to the elected species only.

Priority

The following was originally stated in the Office action dated 12/8/2008 and is restated here for convenience:

Acknowledgement is made that the instant application is a 371 of PCT/IB04/52433 filed 11/15/2004, which claims benefit of 60/520279 filed 11/14/2003 and claims benefit of 60/599509 filed 8/6/2004. Note is made that the elected species, compound 90, page 38 of the specification, also the compound of instant claim 39, has support back to the earliest filed provisional application, 60/520279 filed 11/14/2003.

Information Disclosure Statement

Acknowledgement is made of applicant's submitting an information disclosure statement on 12/15/2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. Reference WO00/78761 was lined out because the Examiner cited this reference on form PTO-892 in the Office action 12/8/2008. The listing of this reference in the IDS dated 12/15/1008 is redundant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

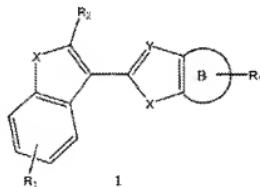
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1611

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22, 24-27 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bannister et al. (WO 2000/78761).

Bannister teaches compounds of the following general formula.



Wherein X can be NH, Y can be N, R₂ can be Me, R₁ need not be present and B can be a polycyclic cycloalkyl or heteroaryl, or heterocyclic rings *inter alia* (page 18, also claims 1-20). Pages 10-11 of the disclosure further define the term heterocyclyl or heterocyclic group to mean phenanthroline.

Bannister teaches several examples wherein R₂ is Me, X is NH, Y is N and R₁ is absent. Bannister fails to teach a specific embodiment wherein B is phenanthroline. However, phenanthroline is suggested as a possible B ring from a finite number of possible combinations. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the instant invention, to arrive at the elected species with a

reasonable expectation for success. One would have been motivated to do so because the elected compound is suggested from a finite number of possible combinations.

Response to Arguments

Applicant's arguments filed 3/9/2009 in response to the rejection of claims over Bannister have been fully considered, but are not persuasive. Applicant argues as an initial matter that the Examiner has improperly referenced the claims of Bannister in lodging the rejection (see page 36 of the remarks filed 3/9/2009) and quotes *In re Benno* (1985), 768 F.2d 1340 (Fed. Cir. 1985) as support. This argument is not persuasive. *In re Benno* discusses the fact that claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. Contrary to Applicant's allegation, *In re Benno* does not prohibit the claimed subject matter of a prior art document from being used as prior art. In fact, *In re Benno* states that the claims as originally filed are part of the disclosure. Even assuming that one could not rely upon the claims of a prior art document in support of a rejection, which it is the position of the Examiner that one can, the specification of Bannister, as addressed in the rejection at page 18 discloses the same subject matter as the claims. Please also see pages 19-20 for preferred embodiments which exactly mirror the claims.

Applicant also argues that the Examiner has failed to consider the claimed invention as a whole and as such has not established a *prima facie* case of obviousness. To support this argument applicant argues that the teachings of Bannister are overly

broad. Applicant argues that the compounds of structural formula (I), having a fused ring can be selected from a near, in applicant's words "incalculable" number of possible combinations. Applicant further argues that none of the exemplary compounds of Bannister are directed to polycyclic ring systems (i.e. phenanthroline) as required by the instant claims. These arguments are not persuasive.

Applicant's attention is directed to claims 2, as well as 7-10 (see also specification pages 19-20) which are directed to compounds of formula (I) having a fused aromatic or heteroaromatic ring. This subgenus is much smaller than the genus of "fused rings" to which applicant's arguments are directed. Pages 10 and 11 are directed to the specific examples encompassed by fused aromatic and heteroaromatic ring systems. Of the finite number of possible options, phenanthroline is listed as a possible option on page 11. Whereas it is true that such "picking and choosing" within several variables does not necessarily give rise to anticipation, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter

of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is...a person of ordinary creativity, not an automaton." *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have arrived at the instantly claimed compounds and specifically the elected species, which is the compound of claim 39 having a fused phenanthroline ring, as compounds having this functionality were suggested by Bannister as a possible option. From the teachings of Bannister, the ordinarily skilled artisan could have arrived at the elected compound of the instant invention with a reasonable expectation of success. Applicant has not provided evidence to the contrary.

Applicant argues also that the instant compounds have disclosed properties as anti-cancer agents and that the compounds disclosed in Bannister have antibacterial and/or antiinfective effects. This argument is not persuasive to rebut the *prima facie* case of obviousness. The intended ultimate use of a compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant situation, there is nothing from the disclosure of Bannister which would prevent the compounds taught therein from being used as anti-cancer agents. The instant claims are directed to compounds which the teachings of Bannister make obvious. Applicant has not provided evidence to rebut this *prima facie* case of obviousness.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-22, 24-27 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25 and 42 of copending Application No. 10/525690. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a compound of formula VI and the co-pending claims of application '690 are also drawn to a compound of formula VI. The definitions of substitutents of these two formulae overlap significantly and only vary in a few instances (i.e. the instant R6 is slightly more limited than R6 of co-pending '690). Claims 25 and 42 generically encompass the elected species of the instant application. It would be obvious to arrive at the elected species, as it is suggested from a finite listing of possible combinations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-22, 24-27 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 of copending Application No. 11/915257. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a compound of formula VI and the co-pending claims of application '257 are drawn to compounds of formula I, which have a phenanthroline backbone and are structurally very similar to compounds of instant formula IV. The definitions of substituents of these two formulae overlap significantly and only vary slightly in scope. The claims of application '257 recite various intended uses. However, a recitation of the intended use of a compound must result in a structural difference between the claimed invention, absent this difference, the compounds of application '257 and the instant compounds are indistinguishable. Application '257 teaches the elected species of the instant application. This compound is numbered "3" in application '257.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

In the response filed 3/9/2009 applicant acknowledges the double patenting rejection and states that a formal response will be filed once claims are found allowable.

Accordingly, the double patenting rejections over co-pending applications 10/525690 and 11/915257 are maintained.

Conclusion

Claims 21-22, 24-27 and 39 are rejected. No claim is allowed.

No new ground(s) of rejection were presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611